



COPY OF PAPER  
ORIGINAL NOT FILED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of  
Pal Maliga, et al.

Application No.  
09/762,105

Filed: April 23, 2001

For: TRANSLATIONAL CONTROL  
ELEMENTS FOR HIGHER PLANTS  
AND METHODS OF USE THEREOF

Examiner: Kubelik, Anne R.

Group Art Unit: 1638

Response to Paper No. 5

RECEIVED

AUG 14 2002

TECH CENTER 1600/2900

Certificate of Mailing Under 37 CFR §1.8(a)

I hereby certify that this Correspondence is being deposited on August 5, 2002 with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER OF PATENTS AND TRADEMARKS, Washington, DC 20231.

8/5/02  
Date of Certificate

Kathleen D Rigaut  
Kathleen D. Rigaut, Ph.D.

Petition for Extension Under 37 CFR §1.136(a)

The undersigned hereby petitions for an extension of time of One (1) month beyond the time period set in the last office communication. The proper fee under 37 CFR §1.17 is enclosed.

Kathleen D Rigaut  
Kathleen D. Rigaut, Ph.D., J.D.

[ X] Additional Fee is required.

The Commissioner is authorized to charge the \$55.00 fee to the account of the undersigned attorneys, Account No. 04-1406. A duplicate copy of this sheet is enclosed.

DANN, DORFMAN, HERRELL AND SKILLMAN  
A Professional Corporation

By

Kathleen D Rigaut  
Kathleen D. Rigaut, Ph.D., J.D.  
PTO Registration No. 43,047

Telephone: (215) 563-4100  
Facsimile: (215) 563-4044

BEST AVAILABLE COPY



COPY OF PAPERS  
ORIGINALLY FILED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of ) Examiner: Kubelik, Anne R.  
Maliga et al. ) Group Art Unit: 1638  
Application No.: 09/762,105 ) Response to Paper No. 5  
Filed: 04/23/2001 )  
For: TRANSLATIONAL CONTROL )  
ELEMENTS FOR HIGHER PLANTS )  
AND METHODS OF USE THEREOF )

RECEIVED  
AUG 14 2002  
TECH CENTER 1600/2900

PRELIMINARY AMENDMENT

Please amend the above identified patent application as follows:

In the claims:

A<sup>1</sup>  
4. (Amended) A recombinant DNA construct as claimed in claim 1, said 5' regulatory region being selected from the group consisting of PrrnLT7g10+DB/Ec, SEQ ID NO:14, PrrnLT7g10+DB/pt, SEQ ID NO:15, PrrnLT7g10-DB, SEQ ID NO:16.

A marked-up copy of the amendment is provided in Appendix A.

TRAVERSAL OF RESTRICTION REQUIREMENT

Sir:

In the Requirement for Restriction under 35 U.S.C. §121 and 372 set forth in the Official Action dated June 5, 2002, in the above-identified application it is the Examiner's position that the inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, and that the inventions must be restricted to the following Groups:

08/12/2002 NMOHAMM1 00000036 041406 09762105

01 FC:215 55.00 CH

BEST AVAILABLE COPY

Group I: Claims 1-26, drawn to a DNA construct comprising a promoter element, a leader sequence, and a downstream box element, and a method for its use for enhanced plastid expression of a heterologous gene.

Group II: Claims 27-28, drawn to a method for modifying codon usage in structural genes.

Further, if the invention of Group I is elected, the Examiner requires that a single nucleotide sequence be selected for this Group.

The Examiner argues that the technical feature of Group I does not constitute a special technical feature, because Zoubenko et al., Nucleic Acids Research, 22:3819-3824 teach a chloroplast expression vector comprising an *rrn* promoter and heterologous *aadA* gene encoding a streptomycin resistance protein, wherein the promoters and constructs would inherently comprise the native leader sequence and the downstream box element.

The Examiner concludes by stating that nucleotide sequences are structurally distinct compounds and are unrelated to one another, and thus the sequences are deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121, absent evidence to the contrary.

#### **Election**

In order to be fully responsive to the above-mentioned requirement, Applicant hereby elects, with traverse, Group I, Claims 1-26, drawn to a DNA construct comprising a promoter element, a leader sequence, a downstream box element, and a method of use thereof for enhanced expression of a heterologous gene in a plastid genome. Applicants elect SEQ ID NO: 14, with traverse, to comply with the Examiner's requirement that a single nucleotide species be elected for examination purposes.

**BEST AVAILABLE COPY**

### **Traversal**

Applicants present two arguments in this traversal. Should the Examiner not find the first argument persuasive, she is respectfully requested to consider the second argument.

Applicant traverses on the grounds that there is not an undue search burden to search all of the promoter constructs together, due to the numerous repeated elements in the claimed constructs. Furthermore, at a minimum, SEQ ID NO:14 and SEQ ID NO: 16 could be searched together without an undue search burden.

(1) Applicants submit that while the inventions are distinct, a search of the claimed DNA constructs would not provide an undue search burden, because all of the constructs contain similar, discrete sequence elements and thus could easily be searched together. For example, SEQ ID NO:1-3, 4-5, 6-8, 9-10, 11-13, and 14-16 respectively each contain the same promoter elements (LatpB, LclpP, LrbcL, LpsbB, LpsbA, and LT7g10 respectively), and similarly contain repeating patterns of identical downstream boxes. Thus the claimed inventions are all linked by common promoter elements and downstream boxes, and could be searched together without undue burden, since the sequences are not lengthy (none are longer than 200 nucleotides) and are highly repetitive. It is further noted that shorter, repetitive sequences can be more easily searched. Should the examiner maintain that a search of all of the claimed DNA constructs presents an undue burden, the Examiner is respectfully requested to consider instead presenting these as a species election requirement, as they are all species of similar, discrete promoter elements and downstream box elements.

(2) Should the examiner maintain that it is unduly burdensome to search all of the claimed DNA constructs together, and that a species election is not appropriate, Applicants respectfully request that the DNA constructs of SEQ ID NO:14 and 16 be included in the same Group. It is

Applicant's position that SEQ ID NO:14 and 16 could be searched and examined together, without undue burden to the Examiner, because the sequence of SEQ ID NO:16 is a truncated version of SEQ ID NO:14 and thus a search of SEQ ID NO:14 would inherently provided a complete search for SEQ ID NO:16.

Applicants submit the following homology alignment as evidence that the search of SEQ ID NO:14 and 16 would not present an undue search burden.

**Sequence Alignment for SEQ ID NO:14 and 16**

Top Line = PrnnLT7g10+DB/Ec(SEQ ID NO:14)

Bottom Line =PrnnLT7g10-DB(SEQ ID NO:16)

gagctcgctc cccgcgcgtc gttcaatgag aatggataag aggctcgtag gattgacgtg	60
gagctcgctc cccgcgcgtc gttcaatgag aatggataag aggctcgtag gattgacgtg	60
agggggcagg gatggctata ttctgggag ggagaccaca acggttccc actagaaata	120
agggggcagg gatggctata ttctgggag ggagaccaca acggttccc actagaaata	120
attttggta actttaagaa ggagatatac atatggcaag catgactggt ggacaggctag c	182
attttggta actttaagaa ggagatatac atatggc--- ----- -----tag c	

This alignment demonstrates that SEQ ID NO:16 is fully comprised within SEQ ID NO:14.

A similar argument can be made for the other sequences of Applicants claims which are truncations of one another, such as SEQ ID NO: 1 and 2, SEQ ID NOS: 4 and 5, etc. Clearly a withdrawal or at the very least, a modification of the restriction requirement is in order.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.